Overview of Radiation Regulations

Radiation Control Program 2006 Workshop

by

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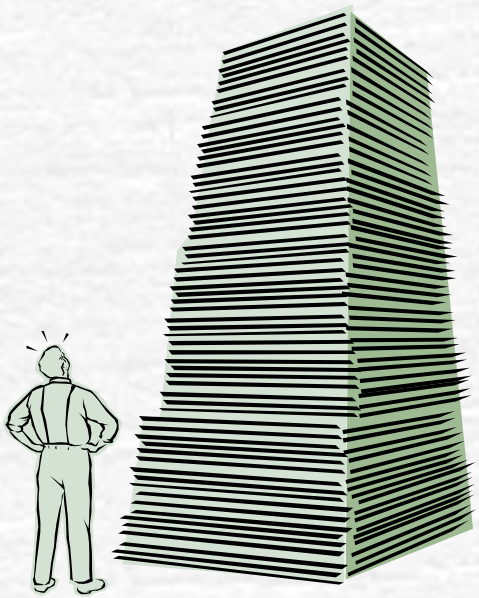
Objectives

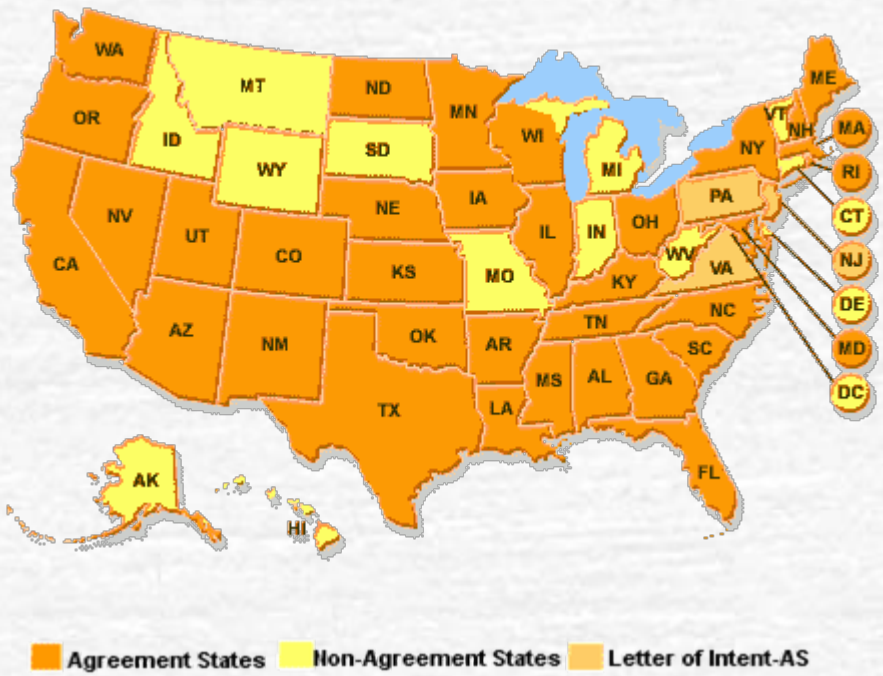
- Understand the regulatory process
- Describe the major changes in the radiation regulations
- Describe how these changes affect the regulated community

Why This Monstrous Package



- The old regulations were:
  - Not compatible with Federal or other State's Regulations
  - Out of date with technology
  - Not user friendly
    - Errors in cross referencing
    - Difficult to find things
    - Not consistent with other states

Radioactive Materials



- 34 Agreement States
- 16 NRC States (3 have Applied for Agreements)
- Regulate most radioactive material
  - Byproduct
  - Source material
  - Special Nuclear Material (< critical mass)

Radioactive Material and Radiation Producing Devices

- Conference of Radiation Control Program Directors (CRCPD)
  - Nonprofit, voluntary, scientific and professional society
  - All State's Radiation Control Directors and Staff
  - Suggested State Regulations for Control of Radiation
    - Consistency across all states
    - Compatible with NRC
- Food and Drug Administration

Compatibility

- NRC levels of compatibility
  - A – Terms, must mean the same
  - B – Program element with same meaning
  - C – Program element can be more restrictive
  - D – Not required for compatibility
  - NRC – Reserved for NRC
  - H&S – Not required but significant health and safety impact
- NRC reviews for compatibility and submits comments to public hearing

Achieving Compatibility and Consistency

- Sources for regulations
  - Existing Kansas Regulations
  - NRC Regulations
  - Suggested State Regulations
- Incorporated into Kansas regulatory language
- Adopted by reference
- Ensures Kansas is compatible and consistent with NRC and the other States

Out of Date with Technology

NRC and SSCRs address the latest technologies

- SSCRs are:
  - Consensus of the 50 states
  - Reviewed by NRC, EPA and FDA
- Using these as templates ensures up to date regulations

Old style fluoroscopy

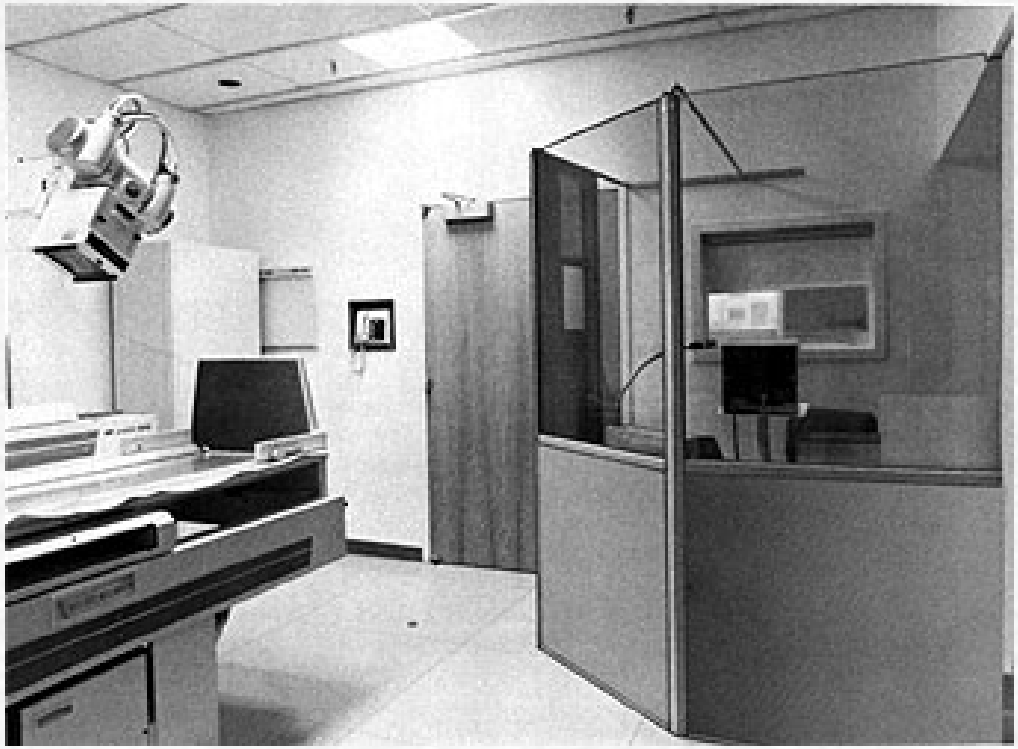
User Friendliness

- New organization patterned after SSCRs
- Modularized
- More logical flow (i.e. definitions are alphabetical)
- Better language, less open to interpretation
- Corrected incorrect references and eliminated unnecessary references
- Easier to maintain, can change one regulation without changing others

Part 1: General

- The definitions of terms that are used in Article 35 were organized alphabetically for easier access, and to be consistent with the general format of Kansas' regulations.
- K.A.R. 28-35-148 provides for enforcement action against any person who willfully violates or causes a licensee or registrant to violate regulations in Article 35.

Part 2: Registration of Radiation Producing Devices



X-ray room with operator's booth

- Regulations for X-ray facility shielding plans and operator booth construction were moved from Part 5. 28-35-167, 168 & 169

Part 3: Licensing Of Sources Of Radiation

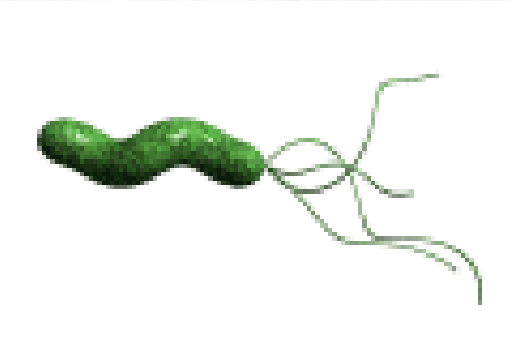
- Ensures compatibility with NRC
- Clarifies the contents of license applications for several categories.

28-35-178b(a)(3)

Generally licensed process monitor

- Enhances the accountability and security of large generally licensed devices by requiring them to be specifically licensed
- Unless specifically exempt all other generally licensed devices are registered and a responsible individual designated.

Specifics of Part 3 Changes



H. Pylori bacteria

- 28-35-178j. General license for use of byproduct material for certain in vivo clinical or laboratory testing. Exemption for the H. Pylori test.

Specifics of Part 3 Changes

- 28-35-180b. Financial assurance for decommissioning. Moved from 18-35-180a.
  - Increased default amounts
  - Licensees have the option to do a site specific cost analysis.

Specifics of Part 3 Changes

Dose prep area

- 28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals.
- Radiopharmacy rule:
  - Qualified nuclear pharmacists.
  - Proper labeling and packaging
  - Quality testing of radiopharmaceuticals
  - Meet FDA & other State requirements

Specifics of Part 3 Changes

- 28-35-181s. Specific licenses for well logging.
- 28-35-185a. Expiration of licenses. Licensee responsible even if they fail to renew the license.
- 28-35-204. Decommissioning plan. Timely clean up under an approved plan.
- 28-35-205. Criteria for termination without restrictions. 25 mrem per year limit.

Specifics of Part 3 Changes

- 28-35-205a. Criteria for termination with restrictions (i.e. deed restrictions, covenants, etc.). 25 mrem per year limit.
- 28-35-205b. Alternate criteria for license termination. Provides for termination with doses up to 100 mrem per year with justification.

Specifics of Part 3 Changes

- 28-35-206. Applicability of decommissioning requirements following license termination. Allows KDHE to require additional clean up if new information shows the criteria were not met.

Part 4: Standards For Protection Against Radiation

- A mechanism is provided by which a registrant may request the use of weighting factors to determine personnel exposure if a protective apron is worn by medical fluoroscopists performing special and interventional fluoroscopic procedures.

Specifics of Part 4 Changes

- Decommissioning plans are required.

Removing First Soil Layer

Specifics of Part 4 Changes

- 28-35-211d. Radiation protection programs. Establishes 10 mrem limit from air emissions for compatibility with EPA regulations.
- 28-35-213b. Dose to an embryo or fetus. Clarifies monitoring requirements.

Specifics of Part 4 Changes

- 28-35-231a. Vacating installations. Requires notification and timely decommissioning when a facility is vacated.
- 28-35-231c. Transfer for disposal; manifests. Adopts federal manifest requirements by reference.

Part 5: Use Of X-rays In The Healing Arts

- This Part has been reorganized into a more logical structure and enhanced to accommodate the latest technological advances in diagnostic X-ray.
- The requirements for therapeutic radiation machines have been enhanced and moved to Part 14 Therapeutic Radiation Machines.

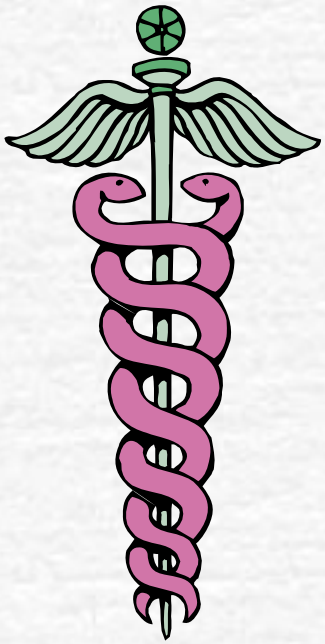
Specifics of Part 5 Changes

- Codifies current industry practices for the operation and maintenance of computed tomography machines.

Specifics of Part 5 Changes

- 28-35-253 and 254 were moved to Part 2 (Shielding plan and operators booth)
- 28-35-255. Healing arts screening. Clarifies information needed for approval of screening.
- Exempts Certified Mammography facilities from screening approval.
- 28-35-256. Training for X-ray system operators. Clarifies training for machine operators, ties in with Board of Healing Arts

Part 6: Use Of Radioactive Materials In The Healing Arts



- 10 CFR 35 is adopted by reference and substantially reduces the regulatory burden on medical licensees.
- Patient release criteria is relaxed based on potential dose to caregivers. This will significantly reduce the burden and cost to patient, hospital and insurance companies.

Part 7: Industrial Radiographic Operations

Radiography in progress

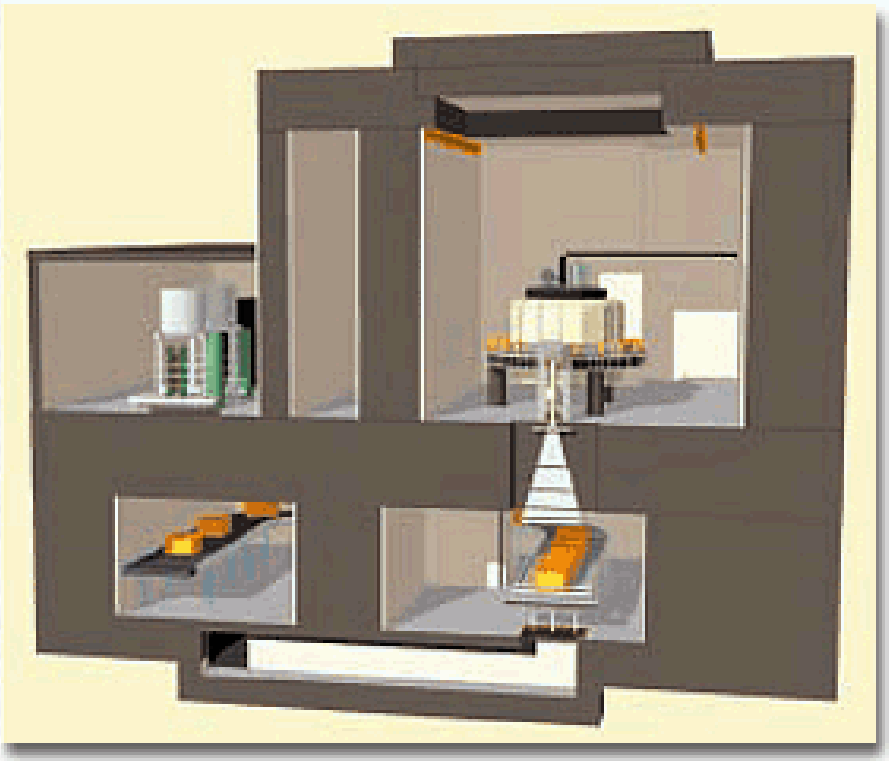
- Codifies 2-man rule implemented by license condition.
- Corrects an error that required personnel monitoring for cabinet X-ray systems specifically designed such that the operators do not need personnel monitoring.

Part 8: Requirements For Analytical X-ray Equipment

X-ray Fluorescence Analyzer

- Confirmation that the X-ray tube is off and will remain off until safe conditions have been restored during repairs and prohibits relying on interlocks during repairs.
- Clarifies when radiation surveys are required.

Part 9: Requirements For Particle Accelerators



"E-beam" food irradiator

- Corrects references to regulations changed in other parts
- Reduces regulatory burden by changing the calibration of area radiation monitors from quarterly to annual

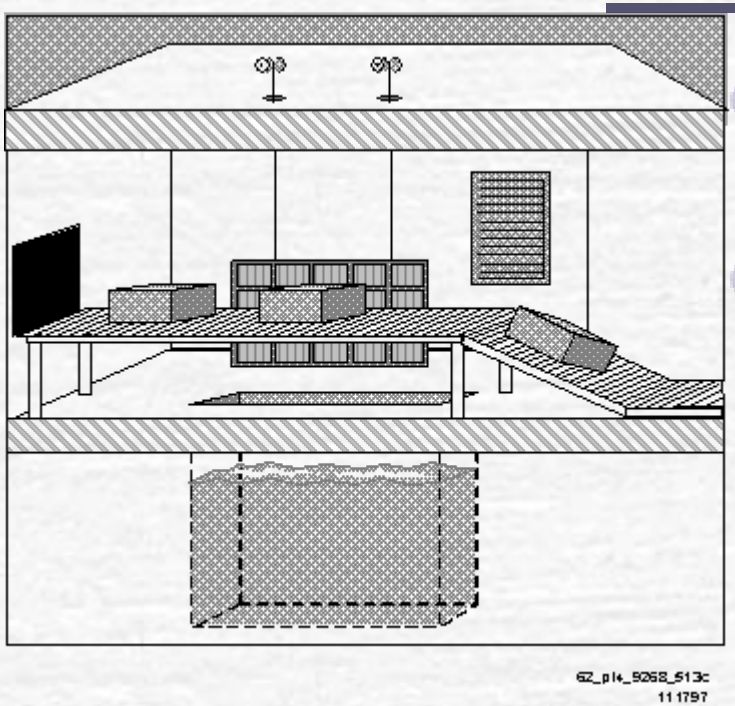
Part 10: Instructions And Reports To Workers: Inspections

- Reduces the regulatory burden by requiring annual training only for those individuals who are likely to receive an exposure in excess of the limit for members of the public

Part 11: Wireline And Subsurface Tracer Studies

- Regulations were amended and added to ensure compatibility with the NRC and other States
- Reduces the regulatory burden by allowing:
  - use of uranium sinker bars, energy compensation sources, and
  - sealed sources in a well without a surface casing
- Requires sources be secured, tested and inspected
- Requires a logging supervisor be physically present when sources are in use.
- Clarifies training, operating and emergency procedures, and radiation surveys.

Part 12: Licensing And Radiation Safety Requirements For Irradiators



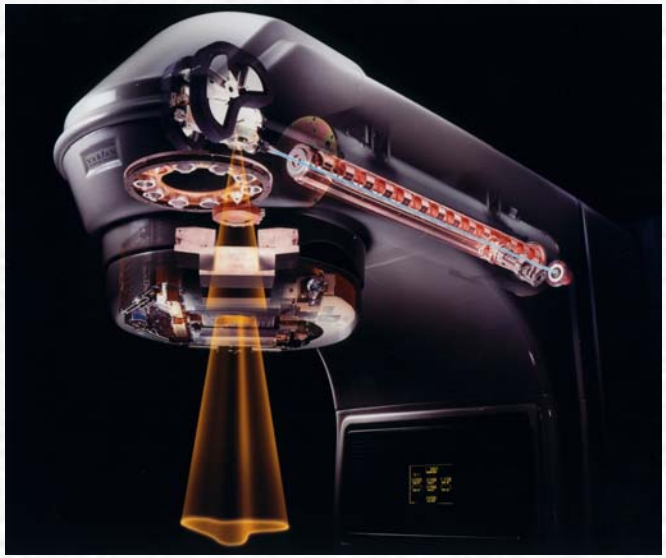
Wet source storage irradiator

- Adopts 10 CFR 36 by reference.
- Currently, there are no licensees using irradiators that fall under these regulations, however, should a facility desire to install an irradiator the licensing requirements will be in place.

Part 13: Contingency Planning For Response To Radioactive Material Emergencies

- The requirements of K.A.R. 28-35-193b Emergency Plan Criteria were enhanced and moved to this part to raise the level of awareness to this area important to homeland security.
- Currently, there are no licensees required to have an emergency contingency plan in place, however, should a facility desire to increase the amount of radioactive material they are licensed for, the licensing requirements will be in place.

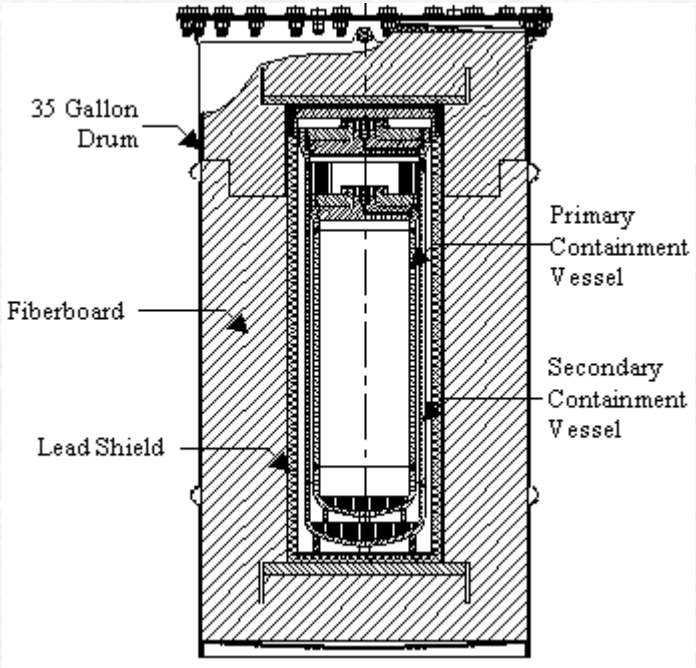
Part 14: Therapeutic Radiation Machines



Varian Linear Accelerator

- Moved from Part 5
- Adopts Part X of the CRCPD Suggested State Regulations (SSR)
- Codifies existing industry standards.
- Old regs were outdated and contradictory to current standards. This new Part corrects these discrepancies.

Part 15: Packaging And Transportation Of Radioactive Material



Model 9975 Type B Package

- New part for compatibility with NRC regulations
- No users of Type B packages licensed by Kansas except industrial radiographers.
- Part 7 covers these

??? Questions ???

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